

**REMARKS**

Claims 1, 5 and 17 are amended to define the proton-coupled transporter as peptide transporter 1 (PEPT1). Support for the amendments can be found, for example, at page 7, line 22; page 9, line 26 and Examples 1 and 3-5 of the present specification. Claims 2-4, 6-13, 15, 16 and 18-21 are canceled. Accordingly, claim 5 is also amended to depend from claim 1. No new matter is added. Upon entry of the Amendment which is respectfully requested, claims 1, 5, 14, 17 and 22 will be pending.

**Response to Claim Rejection under 35 U.S.C. § 103(a)**

At page 3 of the Office Action, claims 1-9, 14, 17 and 22 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,660,300 (Timmings).

The Examiner cites Timmins as disclosing a gastrointestinally-absorbed, pharmaceutical preparation comprising a mixture of a compound recognized by a proton-coupled transporter and a pH-sensitive polymer, which renders obvious the present invention. The Examiner asserts that Timmins discloses that the pharmaceutical formulation will have a total polymer extended release content (*i.e.*, hydrophilic and/or hydrophobic polymers in the inner and outer phases) ranging as broadly as about 25 wt% to about 75 wt% and preferably ranging from 35 to 60% by weight of the entire composition.

Applicants traverse and respectfully request the Examiner to reconsider in view of the following remarks.

The present invention relates to a pharmaceutical preparation exhibiting gastrointestinal absorability comprising a mixture of a compound recognized by a peptide transporter 1, and a pH-sensitive polymer, as recited in amended claim 1. The pH-sensitive polymer is present in an amount sufficient to impart to the gastrointestinal tract a pH at which the peptide transporter 1

optimally functions for cellular uptake of the compound. The pH-sensitive polymer is at least one member selected from the group consisting of dried methacrylic acid copolymer, methacrylic acid copolymer LD, methacrylic acid copolymer L, methacrylic acid copolymer S, polyacrylic acid, maleic acid/n-alkyl vinyl ether copolymer, hydroxypropylmethylcellulose acetate succinate, and hydroxypropylmethylcellulose phthalate. The amount of the pH-sensitive polymer being 5 to 40 wt % based on the weight of the entire pharmaceutical preparation.

The present invention also relates to a pharmaceutical preparation for enhancing gastrointestinal absorbability of a compound recognized by a peptide transporter 1, the pharmaceutical preparation comprising a mixture of the compound recognized by a peptide transporter 1; and a pH-sensitive polymer in an amount sufficient for the gastrointestinal tract to acquire a pH at which the peptide transporter 1 optimally transports the compound into a cell, as recited in amended claim 17. The pH-sensitive polymer is at least one member selected from the group consisting of dried methacrylic acid copolymer, methacrylic acid copolymer LD, methacrylic acid copolymer L, methacrylic acid copolymer S, polyacrylic acid, maleic acid/n-alkyl vinyl ether copolymer, hydroxypropylmethylcellulose acetate succinate, and hydroxypropylmethylcellulose phthalate. The amount of the pH-sensitive polymer being 5 to 40 wt% based on the weight of the entire pharmaceutical preparation.

In the present invention, it is important to add a specific amount of pH-sensitive polymer so that the pH of the gastrointestinal tract is adjusted to a value optimal to a peptide transporter 1. Such an addition is conducted for the purpose of adjusting the pH of the gastrointestinal tract, which tends to be neutral or alkaline, to a value at which the peptide transporter 1 optimally functions for cellular uptake. The “pH-sensitive polymers” refer to polymers that release protons depending upon the pH of the specific site such as gastrointestinal tract, for example, polymers

that dissolve or swell by releasing protons under high pH conditions. (See page 13, lines 16-25 of the present specification).

Applicants respectfully submit that the present claimed invention, as defined by amended claims 1 and 17, is not rendered obvious by Timmins because Timmins at least fails to disclose, teach or suggest a peptide transporter 1 and a pH-sensitive polymer being 5 to 40 wt% based on the weight of the entire pharmaceutical preparation, as recited in amended claims 1 and 17. In addition, the Examiner has not adequately identified a reason that would have led a person of ordinary skill in the art in the relevant field to arrive at the presently claimed pharmaceutical preparation comprising a peptide transporter 1 and a pH-sensitive polymer being 5 to 40 wt% based on the weight of the entire pharmaceutical preparation, as defined in amended claims 1 and 17.

To maintain the rejection under 35 U.S.C. § 103, the cited reference Timmins must teach or suggest each and every element of the claims 1 and 17. As noted above, Timmins fails to specifically disclose a pharmaceutical preparation comprising a peptide transporter 1 and a pH-sensitive polymer being 5 to 40 wt% based on the weight of the entire pharmaceutical preparation. In addition, it is necessary to identify “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007). As explained below, the Examiner has failed to provide such a reason.

The Examiner’s position is that Timmins teaches a biphasic-controlled release system having both an inner solid particulate phase and an outer sold continuous phase in a ratio from 0.5:1 to 4:1. The Examiner states that Timmins teaches that both the inner and outer phases comprise hydrophobic polymers preferably ranging from 35 to 60% by weight of the entire

composition and hydrophilic polymers which include methacrylic acid copolymers "L" and "S" or Eudragit L and Eudragit S. However, Applicants respectfully submit that the broad teaching of hydrophobic polymers in Timmins would not guide one of ordinary skill in the art to arrive at the presently claimed composition. At col. 10, lines 44 to 55, Timmins broadly lists various examples of hydrophobic polymers that *could* be employed in the inner solid particulate phase and/or outer solid continuous phase to make the pharmaceutical formulation. Timmins discloses pH-sensitive polymers (*e.g.*, Eudragit RL, Eudragit L and/or S) that have a carboxyl group (-COOH) in the molecule and that release protons. Timmins also lists, in a parallel manner, pH-insensitive polymers (*e.g.*, ethyl cellulose, hydroxyethylcellulose, Eudragit L 100-5, Eudragit NE30D, Eudragit E, and vinyl methyl ether/maleic anhydride copolymers) that cannot release protons. Additionally, Timmins discloses that other hydrophobic material that may be employed include, but are not limited to waxes, fatty alcohols and fatty acid esters. Timmins does not teach why selecting a pH-sensitive polymer, such as Eudragit L and/or S, would be desirable. Furthermore, Timmins discloses hydroxypropylmethylcellulose, which is a pH-insensitive polymer, in Examples 1-4, suggesting that the use of a pH-insensitive polymer is preferable.

A copy of the document that provides information regarding "Eudragit" (*i.e.*, Eudragit L 100-55, Eudragit RS PO, Eudragit NE 30 D, Eudragit RL 100, Eudragit RS 100, Eudragit E 100, Eudragit L 100 and Eudragit S 100) is enclosed herewith.

Even if a pH-sensitive polymer such as Eudragit L and/or Eudragit S is somehow selected from among the various choices of hydrophobic polymers, Timmins does not disclose, teach or suggest that the pH sensitive polymer is present in an amount of 5 to 40 wt% based on the weight of the entire pharmaceutical preparation. Timmins does not recognize the importance of the presence of the pH-sensitive polymer, particularly, that the presence of pH-sensitive polymer (in

an amount of from 5 to 40 wt%) imparts to the gastrointestinal tract a pH at which the peptide transporter 1 optimally functions for cellular uptake of the compound. Since the amount of pH-sensitive polymer is not recognized in Timmins to be result effective, one of ordinary skill in the art would not arrive at the claimed range in view of Timmins.

Based on the disclosure of Timmins that the total polymer extended release material content is preferably from about 35 to about 60 by weight based on the total weight of the pharmaceutical formulation, the Examiner contends that the presently claimed amount of the pH-sensitive polymer being 5 to 40 wt % is within the range taught by Timmins. However, an amount/range of pH-sensitive polymer is not disclosed or suggested at all in Timmins. Timmins teaches that the pharmaceutical formulation has a total polymer extended release material content (including hydrophilic polymers and/or hydrophobic polymers and/or other hydrophobic material present in the inner solid particulate phase and hydrophilic polymer and/or hydrophobic polymers and/or other hydrophobic material present in the outer solid continuous phase) within the range of from about 25 to about 75% by weight, preferably from about 35 to about 60 by weight based on the total weight of the pharmaceutical formulation. However, Timmins does not expressly disclose an the amount of the pH-sensitive polymer based on the weight of the entire pharmaceutical preparation.

The Examiner has failed to establish *prima facie* obviousness of the presently claimed composition because there is no guidance to specifically select the pH-sensitive polymer or arrive at an amount of 5 to 40 wt% of the pH-sensitive polymer based on the weight of the entire pharmaceutical preparation, as recited in the presently claimed invention. Timmins only provides a very general disclosure that among various hydrophobic polymer, a pH-sensitive polymer such as Eudragit L and/or S may be used to comprise an inner solid particulate phase

and/or outer solid continuous phase to make the pharmaceutical formulation, failing to provide any additional guidance on why Eudragit L and/or S should be used or how one having ordinary skill would arrive at the pH-sensitive polymer in an amount of 5 to 40 wt% of the entire pharmaceutical preparation. Thus, without any additional guidance, one of ordinary skill in the art would not have had a reasonable expectation of success in arriving at the presently claimed invention.

For at least these reasons the present invention is not rendered obvious by Timmins.

Furthermore, the working Examples of the present invention provide evidence of the superior effects of the present invention.

Example 2 and Fig. 2 of the present specification disclose an evaluation of the pH profile of a buffer, changing the amount of a methacrylic acid copolymer (Eudragit L 100-55) which is a pH-sensitive polymer, and the amount of an aminoalkyl/methacrylate copolymer (Eudragit RS PO) which is a pH-insensitive polymer. A reduction of pH was observed in a concentration dependent manner when Eudragit L 100-55 (pH-sensitive polymer) was added, but no reduction in pH was observed when Eudragit RS PO (pH-insensitive polymer) was added. The Eudragit RS PO comprises an ester group having a quaternary ammonium group ( $-N^+Me_3 \cdot Cl^-$ ) and has a structure similar to that of the pH-insensitive polymers disclosed in Timmins on page 10, lines 44 to 55 (e.g., Eudragit RL, and Eudragit RS).

Example 3 and Figs. 3A and 3B of the present invention disclose that the uptake of the substrates (CDX and CFIX) was remarkably increased by using a pH-sensitive polymer in such an amount that optimizes the pH for a peptide transporter 1. In Example 4 and Fig. 4, it was confirmed that when a suitable amount of pH-sensitive polymer (Eudragit L100-55) was used, a

remarkably higher bioavailability was achieved compared to the case where a pH-insensitive polymer (Eudragit RS PO) was used.

Timmins fails to disclose a peptide transporter 1 and a pH-sensitive polymer based on the weight of the entire pharmaceutical preparation, wherein the cellular uptake of a medicament using a pH-sensitive polymer is present in an amount sufficient to impart to the gastrointestinal tract a pH at which the peptide transporter 1 optimally functions. Furthermore, a person having ordinary skill in the art would not have been motivated to arrive at the presently claimed pharmaceutical preparation comprising a peptide transporter 1 and a pH-sensitive polymer being 5 to 40 wt% based on the weight of the entire pharmaceutical preparation, as defined in amended claims 1 and 17, in view of Timmins. Also, the working Examples demonstrate that by employing a pH-sensitive polymer in an amount sufficient for the gastrointestinal tract to acquire a pH at which the peptide transporter 1 optimally transports the compound into a cell, the pharmaceutical preparation of the present invention achieves superior results.

In view of the above, withdrawal of the § 103 rejection of claims 1-9, 14, 17 and 22 is respectfully requested.

### **Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

  
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WASHINGTON OFFICE  
**23373**  
CUSTOMER NUMBER

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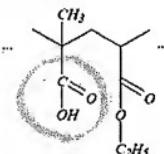


## EUDRAGIT® L 100-55

EUDRAGIT® L 100-55 contains an anionic copolymer based on methacrylic acid and ethyl acrylate.

**Physical properties:** It is a solid substance in form of a white powder with a faint characteristic odour.

**Chemical structure:**



**Pharmacopoeial Monographs**  
more

**Other Enteric Formulations**

EUDRAGIT® L 30 D-55

EUDRAGIT® L 100

EUDRAGIT® L 12,5

EUDRAGIT® S 100

EUDRAGIT® S 12,5

EUDRAGIT® FS 30 D

**Product Form:** Powder

**Targeted Drug Release Area:** duodenum

**Dissolution:** above pH 5.5

**Characteristics:**

- Effective and stable enteric coatings with a fast dissolution in the upper Bowel
- Granulation of drug substances in powder form for controlled release Site specific drug delivery in Intestine by combination with EUDRAGIT® S grades
- Variable release profiles

CAS number: 25212 - 88 - 8

Chemical/IUPAC name: Poly(methacrylic acid-co-ethyl acrylate) 1:1

INCI name: Acrylates Copolymer

**Monographs:**

• Ph. Eur.: Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Type A

USP/NF: Methacrylic Acid Copolymer, Type C - NF

JPE: Dried Methacrylic Acid Copolymer LD

**GMP standard:** The Joint IPEC - PQG Good Manufacturing Practice Guide for Bulk Pharmaceutical Excipients 2006 and USP-NF General Chapter <1078>

**Drug Master File:** # 2584

**Molecular weight information:** approx. 320,000 g/mol

**Acid Value:** 315 mg KOH/g polymer

**Glastransition Temperature (Tg):** -110° C

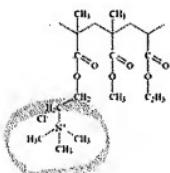


## EUDRAGIT® RS PO<sup>®</sup>

EUDRAGIT® RS PO is a copolymer of ethyl acrylate, methyl methacrylate and a low content of methacrylic acid ester with quaternary ammonium groups. The ammonium groups are present as salts and make the polymers permeable.

**Physical properties:** It is a solid substance in form of white powder with a faint amine-like odour.

### Chemical structure:



### Pharmacopeial Monographs more

#### Other Sustained-Release Formulations

**EUDRAGIT® RL 100**

**EUDRAGIT® RL PD**

**EUDRAGIT® RL 30,D**

**EUDRAGIT® RL 12,5**

**EUDRAGIT® RS 100**

**EUDRAGIT® RS 30,D**

**EUDRAGIT® RS 12,5**

**EUDRAGIT® NE 30,D**

**EUDRAGIT® NE 40,D**

**EUDRAGIT® NM 30,D**

### Product Form: Powder

**Targeted Drug Release Area:** Time controlled release, pH Independent Dissolution:

- Insoluble
- Low permeability
- pH independent swelling

### Characteristics:

- Customized release profile by combination of RL and RS grades in different ratios
- Suitable for matrix structures

CAS number: 33434 - 24 - 1

Chemical/IUPAC name: Poly(ethyl acrylate-co-methyl methacrylate-co-trimethylammonioethyl methacrylate chloride) 1:2:0.1

INCI name: Acrylates / Ammonium Methacrylate Copolymer

### Monographs:

- Ph. Eur.: Ammonio Methacrylate Copolymer, Type B  
USP/NF: Ammonio Methacrylate Copolymer, Type B - NF  
JPE: Aminoalkyl Methacrylate Copolymer RS

Drug Master File: # 1242

Molecular weight information: approx. 32,000 g/mol

## EUDRAGIT® NE 30 D

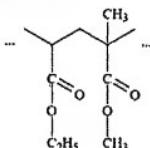


### EUDRAGIT® NE 30 D<sup>®</sup>

EUDRAGIT® NE 30 D is the aqueous dispersion of a neutral copolymer based on ethyl acrylate and methyl methacrylate.

**Physical properties:** It is a milky-white liquid of low viscosity with a faint characteristic odour.

**Chemical structure:**



Pharmacopoeial Monographs  
more

Other Sustained-Release  
Formulations

EUDRAGIT® RL 100

EUDRAGIT® RL PO

EUDRAGIT® RL 30 D

EUDRAGIT® RL 12,5

EUDRAGIT® RS 100

EUDRAGIT® RS PO

EUDRAGIT® RS 30 D

EUDRAGIT® RS 12,5

EUDRAGIT® NE 40 D

EUDRAGIT® NM 30 D

**Product Form:** Aqueous Dispersion 30%

**Targeted Drug Release Area:** Time controlled release, pH Independent  
Dissolution:

- Insoluble
- Low permeability
- pH independent swelling

**Characteristics:**

- No plasticizer required
- Highly flexible
- Suitable for matrix structure

CAS number: 9010 - 88 - 2

Chemical/IUPAC name: Poly(ethyl acrylate-co-methyl methacrylate) 2:1

INCI name: Acrylates Copolymer

**Monographs:**

Ph. Eur.: Polycrylate Dispersion 30 Per Cent

USP/NF: Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion - NF

JPE: Ethyl Acrylate Methyl Methacrylate Copolymer Dispersion

**GMP standard:** The Joint IPEC - PQG Good Manufacturing Practice

Guide for Bulk Pharmaceutical Excipients 2006 and

USP-NF General Chapter <1078>

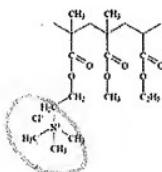


## EUDRAGIT® RL 100<sup>®</sup>

EUDRAGIT® RL 100 is a copolymer of ethyl acrylate, methyl methacrylate and a low content of methacrylic acid ester with quaternary ammonium groups. The ammonium groups are present as salts and make the polymers permeable.

**Physical properties:** It is a solid substance in form of colourless, clear to cloudy granules with a faint amine-like odour.

### Chemical structure:



**Product Form:** Granules

**Targeted Drug Release Area:** Time controlled release, pH Independent Dissolution:

- Insoluble
- High permeability
- pH Independent swelling

### Characteristics:

- Customized release profile by combination of RL and RS grades in different ratios
- Suitable for matrix structures

CAS number: 33434 - 24 - 1

Chemical/IUPAC name: Poly(ethyl acrylate-co-methyl methacrylate-co-trimethylammonioethyl methacrylate chloride) 1:2:0.2  
INCI name: Acrylates / Ammonium Methacrylate Copolymer

### Monographs:

Ph. Eur.: Ammonio Methacrylate Copolymer, Type A  
USP/NF: Ammonio Methacrylate Copolymer, Type A - NF  
JPE: Aminoalkyl Methacrylate Copolymer RS

GMP standard: The Joint IPEC - PQG Good Manufacturing Practice

Pharmacopoeial Monographs  
more

Other Sustained-Release Formulations

EUDRAGIT® RL PO  
EUDRAGIT® RL 30 D  
EUDRAGIT® RL 12,5  
EUDRAGIT® RS 100  
EUDRAGIT® RS PO  
EUDRAGIT® RS 30 D  
EUDRAGIT® RS 12,5

EUDRAGIT® NE 30 D  
EUDRAGIT® NE 40 D  
EUDRAGIT® NM 30 D

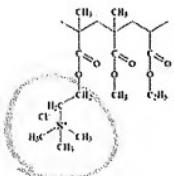


## EUDRAGIT® RS 100

**EUDRAGIT® RS 100** is a copolymer of ethyl acrylate, methyl methacrylate and a low content of methacrylic acid ester with quaternary ammonium groups. The ammonium groups are present as salts and make the polymers permeable.

**Physical properties:** It is a solid substance in form of colourless, clear to cloudy granules with a faint amine-like odour.

### Chemical Structure:



### Product Form: Granules

**Targeted Drug Release Area:** Time controlled release, pH Independent  
**Dissolution:**

- Insoluble
- Low permeability
- pH Independent swelling

### Characteristics:

- Customized release profile by combination of RL and RS grades in different ratios
- Suitable for matrix structures

CAS number: 33434 - 24 - 1

Chemical/IUPAC name: Poly(ethyl acrylate-co-methyl methacrylate-co-trimethylammonioethyl methacrylate chloride) 1:2:0.1

INCI name: Acrylates / Ammonium Methacrylate Copolymer

### Monographs:

- Ph. Eur.: Ammonio Methacrylate Copolymer, Type B  
 USP/NF: Ammonio Methacrylate Copolymer, Type B - NF  
 JPE: Amnoalkyl Methacrylate Copolymer RS

GMP standard: The Joint IPEC - PQG Good Manufacturing Practice

### Pharmacopoeial Monographs more

#### Other Sustained-Release Formulations

- EUDRAGIT® RL 100  
 EUDRAGIT® RL PO  
 EUDRAGIT® RL 30 D  
 EUDRAGIT® RL 12,5  
 EUDRAGIT® RS PO  
 EUDRAGIT® RS 30 D  
 EUDRAGIT® RS 12,5

- EUDRAGIT® NE 30 D  
 EUDRAGIT® NE 40 D  
 EUDRAGIT® NM 30 D

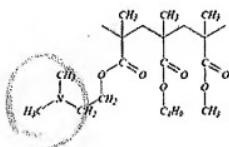


## EUDRAGIT® E 100

**EUDRAGIT® E 100** is a cationic copolymer based on dimethylaminoethyl methacrylate, butyl methacrylate, and methyl methacrylate.

**Physical Description:** It consists of colourless to yellow tinged granules with a characteristic amine-like odor.

### Chemical structures:



**Product Form:** Granules

**Targeted Drug Release Area:** Stomach

**Dissolution:**

- Soluble in gastric fluid up to pH 5.0
- Swellable and permeable above pH 5.0

### Characteristics:

- Low viscosity, high pigment binding capacity, good adhesion
- low polymer weight gain

**CAS number:** 24938-16-7

**Chemical/ IUPAC name:** Poly(butyl methacrylate-co-(2- dimethylaminoethyl) methacrylate-co-methyl methacrylate) 1:2:1

**INCI name:** Acrylates/ Dimethylaminoethyl Methacrylate Copolymer

### Monographs:

|          |  |
|----------|--|
| Ph. Eur. | Basic Butylated Methacrylate Copolymer |
| USP/NF   | Amino Methacrylate Copolymer-NF        |
| JPE      | Aminoalkyl Methacrylate Copolymer E    |

**GMP standard:** The joint IPEC-PQG Good Manufacturing Practice Guide for Bulk Pharmaceutical Excipients 2006 and USP-NF General Chapter <1078>

**Drug Master File:** # 1242

**Molecular weight information:** Mw approx. 47,000 g/mol

**Alkali Value:** 180 mg KOH / g polymer

**Pharmacopoeial Monographs**  
[more](#)

### Other Protective Formulations

[EUDRAGIT® E 12.5](#)

[EUDRAGIT® E PO](#)

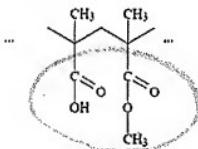


## EUDRAGIT® L 100

EUDRAGIT® L 100 are anionic copolymers based on methacrylic acid and methyl methacrylate.

**Physical properties:** It is a solid substance in form of a white powder with a faint characteristic odour.

### Chemical structure:



**Pharmacopoeial Monographs**  
[more](#)

### Other Enteric Formulations

[EUDRAGIT® L 30 D-55](#)

[EUDRAGIT® L 100-55](#)

[EUDRAGIT® L 12,5](#)

[EUDRAGIT® S 100](#)

[EUDRAGIT® S 17,5](#)

[EUDRAGIT® FS 30 D](#)

**Product Form:** Powder

**Targeted Drug Release Area:** jejunum

**Dissolution:** Dissolution above pH 6.0

### Characteristics:

- Effective and stable enteric coatings with a fast dissolution in the upper bowel
- Granulation of drug substances in powder form for controlled release
- Site specific drug delivery in intestine by combination with EUDRAGIT® S
- grades
- Variable release profiles

**CAS number:** 25086 - 15 - 1

**Chemical/IUPAC name:** Poly(methacrylic acid-co-methyl methacrylate) 1:1

**INCI name:** Acrylates Copolymer

### Monographs

**Ph. Eur.:** Methacrylic Acid - Methyl Methacrylate Copolymer (1:1)

**USP/NF:** Methacrylic Acid Copolymer, Type A - NF

**JPE:** Methacrylic Acid Copolymer L

**GMP standard:** The Joint IPEC - PQG Good Manufacturing Practice Guide for Bulk Pharmaceutical Excipients 2006 and USP-NF General Chapter <1078>

**Drug Master File:** # 1242

**Molecular weight information:** approx. 125,000 g/mol

**Acid Value:** 315 mg KOH/ g polymer

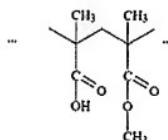


## EUDRAGIT® S 100

EUDRAGIT® S 100 are anionic copolymers based on methacrylic acid and methyl methacrylate.

**Physical properties:** It is a solid substance in form of a white powder with a faint characteristic odour.

### Chemical structure:



### Pharmacopoeial Monographs more

#### Other Enteric Formulations

- EUDRAGIT® L 30 D-55
- EUDRAGIT® L 100-55
- EUDRAGIT® L 100
- EUDRAGIT® L 12,5
- EUDRAGIT® S 12,5
- EUDRAGIT® PS 30 D

**Form of Product:** Powder

**Targeted Drug Release Area:** Colon delivery

**Dissolution:** pH 7,0

### Characteristics:

- Granulation of drug substances in powder form for controlled release
- Effective and stable enteric coatings with a fast dissolution in the upper bowel
- Site specific drug delivery in intestine by combination with EUDRAGIT® S grades
- Variable release profiles

**CAS number:** 25086 - 15 - 1

**Chemical/IUPAC name:** Poly(methacrylic acid-co-methyl methacrylate) 1:2

**INCI name:** Acrylates Copolymer

### Monographs:

Ph. Eur.: Methacrylic Acid - Methyl Methacrylate Copolymer (1:2)

USP/NF: Methacrylic Acid Copolymer, Type B - NF

JPE: Methacrylic Acid Copolymer S

**GMP standard:** The Joint IPEC - PQG Good Manufacturing Practice

**Guide for Bulk Pharmaceutical Excipients 2006 and**

**USP-NF General Chapter <1078>**

**Drug Master File:** # 1242

**Molecular weight information:** approx. 125,000 g/mol

**Acid Value:** 190 mg KOH/ g polymer